

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

KATARZYNA FOULGER, <i>et al.</i> ,)	
)	
Plaintiffs,)	
)	Case No. 4:22-CV-00878
AVERTEST, LLC,)	
d/b/a AVERHEALTH,)	
)	
Defendant.)	

**PLAINTIFFS' MOTION TO COMPEL PRODUCTION OF DOCUMENTS RELATED
TO THE COLLEGE OF AMERICAN PATHOLOGISTS**

This motion relates to objections Defendant Avertest, LLC, d/b/a Averhealth (“Averhealth”) made to Plaintiffs’ requests for documents related to the College of American Pathologists, one of Averhealth’s accrediting organizations, which placed Averhealth on probation for six months from January 29, 2021 to July 29, 2021. Plaintiff moves the Court, pursuant to Fed. R. Civ. P. 37(a)(3)(B)(4) and Local Rule 37, for an Order overruling Averhealth’s “CAP Information Objection” to produce documents in response to Plaintiffs’ Requests Nos. 7, 8, 10, 11, 12, 16, 17, 18, 19, 20, 21, 22, 24, 25, 57, and 83 of Plaintiffs’ Second Request for Production of Documents.

These requests ask for the following:

7. All Documents relating to Averhealth’s accreditation or application for accreditation by CAP.

8. All reports of inspection by CAP.

9. All proficiency testing (“PT”) results from 2018 to the present, including, for each PT result in 2019 and 2020, a Litigation Pack and associated batch record, along with a Litigation Pack and associated batch record for cases tested as part of the same batch.

10. All Documents relating to an inspection of your laboratory by CAP.

11. All Documents relating to the investigation by CAP into Averhealth’s laboratory practices that followed a complaint submitted to CAP by Dr. Sarah Riley in or about November 2020.

12. All Documents submitted to CAP in response to its investigation into Averhealth's laboratory practices that followed a complaint submitted to CAP by Dr. Sarah Riley in or about November 2020.

16. All Documents relating to any or all of the following allegations regarding your practices:

- a. Concern regarding unacceptable quality assurance of mass spectrometry confirmatory testing.
- b. Failure to follow procedures as written.
- c. Concern regarding the manipulation of instrument calibrations.
- d. Concern regarding the review of quality control results.

This request includes but is not limited to the checklist items, as well as the evaluation of bias and root cause analysis in regard to proficiency testing results and the use of historical QC and QC acceptance practices that were mentioned in Dr. Michael B. Datto's letter to Dr. Michele Glinn of January 29, 2021 (*see* Ex. 112 to Amended Complaint).

17. All Documents relating to the decision by CAP to place your accreditation on probation.

18. All Documents relating to the probationary status of your accreditation by CAP in 2021.

19. All Documents submitted by you to CAP regarding your proficiency testing result for 2019, 2020 and 2021.

20. All Documents relating to the consideration of whether to inform clients or others of the probationary status of your accreditation by CAP in 2021 or CAP's decision to place your accreditation on probation.

21. All Documents from January 27 to July 31, 2021, containing or relating to communications by you to anyone not employed by you regarding whether Averhealth was accredited by CAP.

22. All Documents containing or relating to communications by you to anyone not employed by you regarding whether CAP had determined that Dr. Riley's allegations were unfounded.

24. All Documents relating to the non-routine inspection of Averhealth by CAP on or about May 13, 2021.

25. All Documents submitted to CAP as required in the letter from Dr. Datto to Dr. Glinn on or about July 29, 2021 (*see* Amended Complaint ¶ 116).

57. All internal emails relating to ... CAP's investigation of Dr. Riley's allegations [or] the placement of Averhealth's accreditation on probation by CAP

83. All Documents that show that, as of December 2020, "Averhealth has a perfect CAP-FDT proficiency test, a rare industry feat," as stated in Exhibit 219 to the Amended Complaint.

Ex. 1 to Declaration of Richard S. Cornfeld, Ex. A hereto.

In response to each of the requests, Averhealth made what it called a "CAP Information Objection." That objection states:

CAP Information Objection: Many of Plaintiffs' request seek documents and information that are Confidential. The College of American Pathologists ("CAP"). CAP is an approved accreditation organization by the Centers for Medicare and Medicaid Services ("CMS"). Under relevant federal law, CMS grants the CAP Laboratory Accreditation Program "deeming authority," which allows CAP inspections in lieu of a CMS inspection. CMS may disclose accreditation organization inspection results to the public only if the results are related to an enforcement action taken by the Secretary. *See* 42 C.F.R. § 493.571(a). That is due to the confidential nature of the inspection checklists, reports, and findings, all of which are confidential pursuant to CAP's accreditation guidelines:

Confidentiality

All inspection findings are confidential. They should not be discussed in any context other than the inspection itself. Moreover, they should not be disclosed to anyone not associated with the accreditation process unless appropriate prior documented consent has been obtained.

CAP Laboratory Accreditation Manual, 2020 ed.

CAP guidelines also require that inspection materials and other documents used in an inspection be shredded to maintain confidentiality, with any reports that are not shredded contain confidential comments returned to and maintained by CAP, who may only provide them to CMS or a validly authorized oversight agency. CMS also has the power under federal law to issue sanctions, which could include sanctions against Averhealth risking its accreditation under CAP should any confidential information be disclosed. Accordingly, any information related to CAP investigation, actions, or communications are confidential and cannot be

disclosed by Averhealth without violating CAP's regulatory guidelines and risking ongoing accreditation by same, and Averhealth objects to any request to provide such information in violation of its accreditation with CAP and will withhold responsive documents pursuant to this objection.

*Id.*¹

Pursuant to Local Rule 37, Plaintiff attaches, as Ex. A, the Declaration of Richard S. Cornfeld attesting to the Plaintiffs' Counsel's attempt to resolve or narrow by agreement the issues raised by this motion, the parties' inability to reach an agreement, and the nature of the disagreement.

Plaintiffs attach their brief in support of this motion.

Dated: July 28, 2023

Respectfully submitted,

**GOLDENBERG HELLER &
ANTOGNOLI, P.C.**

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¹ Averhealth did not provide a written CAP Information Objection in response to Request No. 9 but orally made that objection during the parties' meet-and-confer.

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CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of July, 2023, the foregoing was served by operation of the Court's electronic filing system on all counsel of record in this matter.

/s/Richard S. Cornfeld